

Plaintiff states that her diet consisted “almost exclusively” of canned tuna for five years between 1999 and 2004. She has been diagnosed with mercury poisoning.

Defendant moves for dismissal, arguing that (1) the United States Food and Drug Administration (“FDA”) preempts state law in the areas of establishing the maximum allowable concentration of methylmercury in fish and of warning consumers about the potential effects of methylmercury in tuna when consumed; (2) Defendant is not liable under New Jersey law for injuries incurred by Plaintiff for abnormal consumption of its product; (3) New Jersey law does not impose a duty upon Defendant to warn potential plaintiffs about a product that may be dangerous only if over-consumed; and (4) Plaintiff’s claim for common law fraud is subsumed by the NJPLA.

DISCUSSION

Motion Requesting Judicial Notice

In support of its motion to dismiss, Defendant requests that this Court take judicial notice of several publicly available reports and articles on methylmercury in fish. The reports are as follows:

- “What You Need to Know About Mercury in Fish and Shellfish,” published by the United States Department of Health and Human Services and the United States Environmental Protection Agency.
- “Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish,” published by the United States Department of Health and Human Services (“DHHS”) and the United States Environmental Protection Agency. (“EPA”).
- Letter from Lester M. Crawford, D.V.M., Ph.D., United States Commissioner of Food and Drugs, to Bill Lockyer,

Attorney General of the State of California, dated August 12, 2005, re: a suit filed on June 21, 2004 in San Francisco Superior Court.

- Section 540.600 of the FDA's Compliance Policy Guide allowance of up to one part of methyl mercury per million non-mercury parts of the edible portion of seafood.

Under Federal Rule of Evidence ("FRE") 201, courts can judicially notice public records.

Lum v. Bank of America, 361 F.3d 217, 222 n. 3 (3d Cir. 2004). FRE 201 states:

A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.

Fed. R. Evid. 201

This Court has consistently held that it may take judicial notice of public records on motions to dismiss. Benak v. Alliance Capital Mgmt. L.P., 349 F.Supp. 2d 882, 889 n. 8 (D.N.J. 2004) (on motion to dismiss court may take judicial notice of publicly available documents and "plaintiffs may therefore be charged with knowledge of relevant public information."). The articles which the Defendant asks this Court to take judicial notice of are all public records and available. This Court, therefore, grants Defendant's motion that this Court take judicial notice of the publicly available information described above.

Methylmercury in Fish

_____ The nature of this action necessitates consideration of the facts regarding mercury in the environment, methylmercury in fish and the FDA's approach to the issue of methylmercury in fish.

Mercury is present in nearly all fish. *See* "What You Need to Know About Mercury in

Fish and Shellfish,” U.S. Dept. of Health and Human Serv. and the United States Env’tl. Prot.

Agency EPA-823-R-04-005 (March 2004) (hereinafter “The Advisory”). Mercury is a naturally occurring element in the environment and is also released into the air through industrial pollution.

Id. Mercury that falls from the air often accumulates in streams, oceans and other bodies of water.

Id. Fish absorb the mercury as they feed in these waters. Id. As a result, mercury becomes part of the fish meat and cannot be removed. Id.

The FDA has established tolerance levels for methylmercury in fish through nutritional guidelines. *See* Fed. Food and Drug Admin. Compliance Policy Guide, § 540.600 (May, 2005).

The FDA has also noted that “[r]esearch shows that most people’s fish consumption does not cause a health concern.” *See* Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish at p. 2 (2004) (hereinafter, “Backgrounder”). Additionally, the FDA states that “[f]ish and shellfish can be an important part of [a recommended] diet.” Id. at 2-3.

Motion to Dismiss

Legal Standard for Granting a Motion to Dismiss

Federal Rule of Civil Procedure 12(b)(6) provides that a court may dismiss a complaint “for failure to state a claim upon which relief can be granted.” In deciding a motion to dismiss under Rule 12(b)(6), all allegations in the complaint must be taken as true and viewed in the light most favorable to the plaintiff. Warth v. Seldin, 422 U.S. 490, 501 (1975); Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc., 140 F.3d 478, 483 (3d Cir. 1998). However, legal conclusions offered in the guise of factual allegations are given no presumption of truthfulness. Chugh v. Western Inventory Serv., Inc., 333 F. Supp. 2d 285, 289 (D.N.J. 2004) (citing Papasan

v. Allain, 478 U.S. 265, 286 (1986)). While a court will accept well-pled allegations as true for the purposes of the motion, it will not accept bald assertions, unsupported conclusions, unwarranted inferences or sweeping legal conclusions cast in the form of factual allegations.

Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997).

Claims Under New Jersey Product Liability and Consumer Fraud Acts

Plaintiff's complaint alleges violations of the NJPLA and NJCFA on behalf of herself individually and on behalf of those similarly situated. The allegations are that Defendant knowingly misrepresented, concealed, suppressed, omitted and failed to disclose material information regarding the presence of methylmercury and other harmful compounds in their tuna products with the intent that Plaintiff and members of the class rely upon such concealment. The complaint also accuses Defendant of negligence, breach of the implied warranty of fitness, and strict liability for failure to adequately warn consumers about the mercury compounds contained in its products.

Defendant argues for dismissal of Plaintiff's complaints under the NJCFA and NJPLA because they are preempted by FDA regulations and advisories which specifically address and regulate the issues of allowable amounts of mercury in its product and whether or not the Defendant is required to warn consumers of the dangers of mercury consumption.

The basis for federal preemption is the Supremacy Clause of the Constitution. Dewey v. R.J. Reynolds Tobacco Co., 121 N.J. 69, 77 (1990). The clause provides that federal law is the "supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. This preemption applies equally to state common law and statutory law. Feldman v. Lederle Lab., 125 N.J. 117, 134 (1991) *cert. denied*, 505 U.S.

1219 (1992).

Whether a federal statute preempts state law turns on the intent of Congress when it passed the law and that intention may be either express or implied. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992). Federal law overrides state law when (1) Congress expressly preempts state law; (2) Congressional intent to preempt can be inferred from the existence of a pervasive federal regulatory scheme; or (3) state law conflicts with federal law or its purposes. English v. General Elec. Co., 496 U.S. 72, 78-79 (1990).

In this case, there is a pervasive federal regulatory scheme implemented by and through the FDA. The FDA has stated that state laws which require warnings regarding methylmercury in fish are preempted under federal law. *See* Letter from Lester M. Crawford, D.V.M., Ph.D., United States Commissioner of Food and Drugs (“Commissioner Crawford”), to Bill Lockyer, Attorney General of the State of California, dated August 12, 2005, re: a suit filed on June 21, 2004, in San Francisco Superior Court (“FDA Letter”).

On June 21, 2004, the Office of the Attorney General of California filed suit seeking an injunction and civil penalties against the Tri-Union Seafoods, LLC, for failing to warn consumers that canned and packaged tuna products were exposing consumers to mercury compounds. The People of the State of California v. Tri-Union Seafoods, LLC, et al., 2006 WL 1544377 (Cal. Super. Case No.: CGC-04-432394). In response to the suit, Commissioner Crawford wrote the FDA Letter which explained that the warnings sought by California would “frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish.” *See* FDA Letter at p. 1.

The FDA Letter also explained that the “FDA has been studying the issue of

methylmercury in fish for several years. In so doing, it has compiled substantial data, and has developed significant expertise in analyzing the pertinent scientific issues, together with the consumer education aspects of this matter. As a result, the agency believes that it is uniquely qualified to determine how to handle the public health concerns related to methylmercury in fish. After many years of analysis on this issue, [the] FDA has chosen to issue an advisory rather than to require a warning on fish and shellfish product labels for several reasons.” *See* FDA Letter at p. 2.

The FDA issued its 2004 methylmercury advisory to, “inform women who may become pregnant, pregnant women, nursing mothers, and parents of young children as to how to get the positive health benefits from eating fish and shellfish, while minimizing their mercury exposure.” *See* FDA Letter at p. 4. The Advisory specifically regulates the levels of methylmercury allowed in canned tuna and specifically rejected the notion that warning labels should be included on cans of tuna. *Id.*

Plaintiff argues that the FDA does not preempt New Jersey state law for failure to warn of the dangers of mercury in the Defendant’s tuna. There is a presumption in the law against preemption. New York Conference of Blue Shield and Blue Cross Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995). The burden is on the proponent of preemption to overcome the presumption against finding that areas traditionally regulated by the states, such as products liability or consumer protection laws, have been preempted. Hillsborough County v. Automated Med Lab., 471 U.S. 707, 716 (1985).

Plaintiff suggests that the Defendant has failed to carry its burden to overcome the

presumption against a finding that either the NJPLA or NJCFA have been preempted by the FDA's actions. In support of its position, Plaintiff states that The Advisory and Backgrounder are not entitled to deference and that the FDA Letter is not persuasive.

Plaintiff explains that the FDA has not officially prohibited mercury warnings on cans of tuna regarding methylmercury. For this proposition, Plaintiff argues that the FDA Letter is not entitled to deference from this Court. "Interpretations contained in formats such as an opinion letter are entitled to respect, . . . but only to the extent that those interpretations have the power to persuade." Christensen v. Harris County, 529 U.S. 576, 587 (2000).

The New Jersey Supreme Court ruled that the lack of a formal FDA requirement for additional warnings on a product does not create a conclusive presumption that labeling which satisfies the FDA also constitutes an adequate warning under state law. Feldman v. Lederle Lab., 125 NJ 117 (NJ 1991), *cert. den.*, 505 U.S. 1219 (1992). As such, if this Court finds that the FDA's regulatory scheme, as described in the Advisory and Backgrounder, is not entitled to deference and that the FDA Letter is not persuasive, then Defendant could comply with both New Jersey and federal law by placing warning labels on their tuna products.

The essential issue is whether the FDA's regulatory scheme as explained and embodied in the FDA Letter, Advisory and other materials is entitled to deference from this Court. In arguing that this Court should not defer to the FDA's interpretation of its regulatory scheme in this area, Plaintiff points to the FDA Letter and calls it too informal. In her brief, Plaintiff states that the FDA Letter "appears to have been solicited for the express purpose of derailing litigation against [Defendant] and other seafood companies." Therefore, Plaintiff reasons, the FDA Letter and

arguments contained therein are not the product of independent analysis by the FDA, but are simply the parroting of arguments designed to benefit the Defendant and other industry members in this and other potential lawsuits.

An examination of the FDA's response to the potential health hazards of methylmercury in food reveals that the FDA has been collecting data and addressing this concern for years. The FDA issued its first methylmercury fish advisory in the mid 1990s. *See* FDA Letter at p. 3. Since that time, the FDA has compiled more data and has developed significant expertise in analyzing the scientific issues and consumer education aspects of this matter.

After studying the data, the Foods Advisory Committee ("FAC") recommended that the FDA and EPA jointly issue an advisory about mercury in fish for women who might become pregnant, women who are pregnant, nursing mothers and young children. *See* Advisory at p.1.

On March 19, 2004, the FDA and EPA released The Advisory, with the following message:

Message to Consumers:

Fish and shellfish are important parts of a healthy and balanced diet. They are great sources of high quality protein and other nutrients. However, depending on the amount and type of fish you consume it may be prudent to modify your diet if you are planning to become pregnant; pregnant; nursing; or a young child. With a few simple adjustments, you can continue to enjoy these foods in a manner that is healthy and beneficial and reduce your unborn or young child's exposure to the harmful effects of mercury at the same time.

See Advisory at p. 1.

The Backgrounder to the Advisory, released simultaneously, clearly emphasizes the

importance of continuing to eat fish as part of a healthy diet:

The Difference Between this Advisory and Previous Advisories:

1. The advisory emphasizes the positive benefits of eating fish.
2. The advisory provides examples of commonly eaten fish that are low in mercury.

* * *

What's Next:

FDA and EPA want to ensure that women and young children continue to eat fish and shellfish because of the nutritional benefits and encourage them to follow the advisory so they can be confident in reducing their mercury exposure as well.

See Backgrounder at p. 2.

Plaintiff argues that the FDA Letter is merely an *ex parte* communication intended to derail litigation against the seafood industry. However, the FDA Letter aside, both the Advisory and Backgrounder excerpted above were released in March, 2004. The California litigation to which the FDA Letter responds commenced on June 21, 2004. Therefore, the Advisory and Backgrounder which evidence a clear effort by the FDA and EPA to encourage the continued public consumption of fish, were released before the complaint in the California case had even been filed. Clearly, the FDA had already taken the position against blanket warning labels before the California suit which prompted the FDA Letter.

In advocating the position that the Advisory and Backgrounder have no preemptive effect on the NJCFA and NJPLA, Plaintiff argues that the mere existence of a federal regulatory or enforcement scheme does not by itself imply preemption. English., 110 S. Ct. at 2279 (1990). Plaintiff's opposition to Defendant's motion to dismiss characterizes the Advisory and

Backgrounder as “minuscule” actions which are not official regulations and, therefore, not sufficient to preempt state law.

However, it is not uncommon for the FDA to specifically choose the issuance of an advisory rather than an official warning. In his letter to the California Attorney General, Commissioner Crawford explained, “[f]irst, consumer advisories are communicated to the target audience directly, rather than to all consumers. Second, the FDA believes that the advisory approach is more effective than a product label statement in relaying the complex messages about mercury in seafood. Third, a label statement that reaches the public at large can also have unintended adverse public health consequences. FDA focus group results have suggested that people who are not in the target audience...might eat less fish or refrain from eating fish altogether when they receive information about the mercury content of fish...”

FDA Letter at p. 2-3.

In holding that a formal explicit agency statement is not necessary for the finding of a preemptive intent, the Supreme Court of the United States explained,

“the Court has never before required a specific formal agency statement identifying conflict in order to conclude that such a conflict in fact exists. Indeed, one can assume that Congress or an agency ordinarily would not intend to permit a significant conflict.

Geier v. Am. Honda Motor Co., 529 U.S. 861, 884-85 (2000).

In Geier, the Supreme Court of the United States examined the Department of Transportation’s interpretation of the regulation at issue’s objectives and the Department’s conclusion that tort suits, like the suit against American Honda Motor Co., would stand as an

obstacle to the accomplishment and execution of those objectives. The Court reasoned that “the agency is likely to have a thorough understanding of its own regulation and its objectives and is ‘uniquely qualified’ to comprehend the likely impact of state requirements.” *Id.* at 883 (*quoting Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996)).

Deference to an agency’s interpretation of its own powers is appropriate when the regulatory scheme is silent as to preemption. *Barnhard v. Thomas*, 540 U.S. 20, 26 (2003). Here, the FDA Letter in response to the California litigation only crystallizes the already transparent intent of the FDA to preempt state law that might interfere with the FDA’s concern that warnings on tuna products may upset the desired balance between informing consumers of both the benefits and risks of fish consumption:

[The] FDA believes that such warnings are preempted under federal law. They frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish; accordingly federal law preempts [California’s] warnings concerning mercury and mercury compounds in tuna. Furthermore, [the] FDA believes that compliance with both the FDA and [the California warning] is impossible and, as a result, the latter is preempted under federal law.

See FDA Letter p. 1-2

Commissioner Crawford also explained that, “rather than requiring warnings for every single ingredient or product with possible deleterious effects, the FDA has deliberately implemented a more nuanced approach, relying primarily on disclosure of ingredient information and nutrition information...in order to avoid overexposing consumers to warnings, which could result in them ignoring all such statements, and hence creating a far greater public health problem.” *Id.*

For the reasons discussed above, this Court finds that the FDA's Advisory and Backgrounder are entitled to deference and that the FDA Letter is persuasive. Therefore, applying the carefully structured and implemented regulatory scheme of the FDA to Plaintiff's allegations that Defendant was required by New Jersey law to provide warnings about methylmercury and that Defendant's failure to warn constituted a violation of the NJCFA, shows that it would be impossible for Defendant to comply with the FDA and New Jersey law.

It is worth noting that the FDA's regulatory approach has been in effect and has preempted New Jersey state law for the entire period that the Plaintiff's diet consisted almost exclusively of canned tuna (1999-2004). The FDA's published its first methylmercury in seafood advisory in the mid-1990s. *See* FDA Letter at p. 3.

The FDA's regulatory scheme is the result of over ten years of data collection and study. Plaintiff suggests that this Court dismiss the FDA's analysis and deliberately nuanced response to the issue of methylmercury found in seafood. To ask that this Court ignore the evidence of the FDA's carefully balanced approach in favor of Plaintiff's claim that the FDA's treatment of this issue is a contrived response to potential lawsuits against the seafood industry distorts logic. This Court will not turn a blind eye to the evidence of the FDA's ten-year deliberately balanced approach to the issue of methylmercury in fish..

This Court, therefore, grants Defendant's motion that Counts I, II and III of Plaintiff's complaint be dismissed.

Claims Under Common Law Fraud

Plaintiff alleges that the actions of Defendant constitute fraudulent conduct, including but not limited to, knowingly making material misrepresentations and omissions regarding Defendant's tuna products upon which Plaintiff reasonably relied. Defendant argues that Plaintiff's common law fraud claims must be dismissed because they are subsumed by the NJPLA.

In Estate of Brown v. Philip Morris, Inc., 228 F.Supp.2d 506 (D.N.J. 2002), the decedent's wife brought suit against three cigarette manufacturers asserting that smoking resulted in the death of her husband and alleging both a violation of the NJPLA and common law fraud. Id. The court held that the NJPLA "clearly subsumes plaintiff's common-law claims." Id. at 516. Put another way, plaintiffs cannot recast a product liability claim as a fraud claim. Walus v. Pfizer, Inc., 812 F.Supp. 41, 45 (D.N.J. 1993).

Count IV of Plaintiff's complaint alleges common law fraud asserting exposure to "unsafe methylmercury and other harmful compounds that could result in mercury poisoning." Counts I and II allege a violation of the NJPLA. As was the case in Estate of Brown, Plaintiff merely "recasts [her] product liability claims" as fraud claims.

Plaintiff's common law fraud claim is pled in violation of the NJPLA's single cause of action rule. This Court, therefore, grants Defendant's motion that Count IV of Plaintiff's complaint be dismissed.

CONCLUSION

Based on the foregoing, Defendant's Motion to Dismiss Plaintiff's complaint is **granted**.

An appropriate Order accompanies this Opinion.

/S Dennis M. Cavanaugh

Dennis M. Cavanaugh, U.S.D.J.

Date: Jan. 8, 2007
